REMARKS

Claims 2 and 7 have been amended in order to recite the present invention with the specificity required by statute. Additionally, Claims 8, 10 and 11 have been amended for better conformity with accepted U.S. practice and/or to better depend from their antecedent claims. Finally, new Claims 22-29 are presented in order to more specifically recite various preferred embodiments of the present invention. The subject matter of the amendment may be found in the specification as filed, *inter alia* at page 24, lines 19-25, page 25, lines 9-20 and Example 4 at pages 42 et. seq. Accordingly, no new matter has been added.

Claim 1 and 18-21 stand withdrawn from prosecution as being directed to non-elected inventions. In response, these claims have been cancelled in order to reduce the issues, together with claims 12-17.

Claim 8 stands objected to as containing a typographical error. In response, this claim has been amended to correct the error noted by the Examiner.

Claims 10, 11, 14 and 15 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. As discussed, claims 14 and 15 were cancelled above. Additionally, claims 10 and 11 have been amended to recite

discrete process steps in conformity with the Examiner's kind suggestion.

Claims 12-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to be supported by an enabling disclosure. Of course, this rejection is mooted in view of the above cancellation of these claims which is effected solely to expedite the prosecution of this application. However, to complete the record, Applicants would like to address the Examiner's statement that use of the invention would require undue experimentation due to failure to disclose patient selection criteria. In that regard, it should be understood that the subject matter of claims 12 and 13 is directed towards a diagnostic agent, e.g., a screen and may therefore be utilized on patients generally. Similarly, claims 14-17 (directed to therapeutic agents etc.) may be desirably utilized on those patients successfully identified, e.g., in claims 12 and 13.

The Examiner also states that the role of SEQ ID NO:1 protein is IgA nephrophathy is unclear, and no assays are taught, there is no indication of therapeutic value for inhibiting expression of that protein. Finally, the Examiner states that antisense technology is very unpredictable and that there is no demonstrated efficacy of protein expression

inhibition.

These statements are simply not well-understood. That is, the Patent and Trademark Office's Training Materials for Examining Patent Applications with respect to 35 U.S.C. §112, first paragraph -- Enablement make plain that the burden of setting forth a factual basis of nonenablement is on the Examiner. However, there is no factual evidence in support of the Examiner's statements. Rather, the statements are conclusory and entirely without any citation in the record whatsoever.

Moreover, the Examiner's statements are, in any event, off point. For instance, it is irrelevant whether or not the role of SEQ ID NO: 1 protein is unclear. Similarly, no assays need be taught since running assays on characterized proteins is per se routine (see, e.g., page 2, lines 3-8). Additionally, those of ordinary skill believe that protein expression exhibition would be therapeutic since excess IgA immune complex in blood is understood to deposit on the glomerulus (page 3, lines 2-4) and antisense technology is already in trials in other areas (page 26, lines 3-7). Accordingly, there were clearly no bases either in law or in fact for this rejection.

Claims 2, 4, 7, 10, 11, 14 and 15 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the present invention.

The rejection of claims 2, 7, 10, 11, 14 and 15 is overcome by the above amendment. Regarding the rejection of claim 4, Applicants respectfully wish to point out that the term is well-known to those of ordinary skill in this art as evidenced by Maniatis, ed., Molecular Cloning, A Laboratory Manual, 2d ed. (1989) Cold Spring Harbor Laboratories. Moreover, in any event, the term is also well-accepted for claim language by the Patent and Trademark Office. That is, a cursory search of the PTO database for U.S. Patent containing both the terms "stringent conditions" and "hybridize" in their claims reveals 71 issued documents (see e.g., claim 1 of U.S. Patent No. 6,054,283; claim 1 of U.S. Patent No. 6,054,269; and claim 3 of U.S. Patent No. 6,040,146, etc., each of which recites "stringent conditions" without further specifying such condition). Accordingly, withdrawal of this rejection is respectfully requested.

Claims 2, 3 and 8-11 stand rejected under 35 U.S.C. §102 as anticipated by Nagase Accession No. 000234, D87078 (claims 2 and 3), and Biolabs Catalogue #1230 (claims 8 and

9), or under 35 U.S.C. §103 as obvious over Nagase in view of Kendrew Encyclopedia of Molecular Biology and Bresser U.S. Patent No. 5,225,356 (claims 8-11). Initially, solely in order to reduce the issues, the rejections over Nagase are all overcome by the accompanying sworn translation (and certified copy) of Applicants' Japanese priority application No. 8-325752. Regarding the remaining rejections, such are clearly overcome by the above amendment which clarifies that claims 8-11 recite the entire sequence or an oligonucleotide of SEQ ID NO:2, which is simply not disclosed in Kendrew or Bresser.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 2-11 and 22-29 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our below listed address.

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